

REMARKS

I. Status Summary

Claims 1, 5, 7, 10-17, 19-26, 28, 29, 31-35, 37-43, 45-58, 60-66, and 68-78 are pending in the present application and have been examined by the United States Patent and Trademark Office (hereinafter "the Patent Office") in a Non-Final Official Action dated March 11, 2008 (hereinafter the "Non-Final Official Action").

Claims 20, 21, and 24 are subject to formal objections.

Claims 1, 5, 7, 10-17, 19-26, 28, 29, 31-35, 37-43, 45-58, 60-66, and 68-78 have been rejected by the Patent Office under the judicially created doctrine of obviousness-type double patenting on several bases as set forth in more detail hereinbelow.

Claims 20 and 21 have been canceled.

Claim 24 has been amended. The amendment is formal in nature to correct a grammatical error, and thus no new matter has been added by any of the amendment to the claim.

New claims 102 and 103 have been added. These claims recite the elements originally recited in claims 20 and 21 (with updated claim dependency for claim 103), and thus support can be found in claims 20 and 21. As such, no new matter has been added by the inclusion of new claims 102 and 103 in the instant application.

Reconsideration of the application as amended and based on the remarks set forth herein below is respectfully requested.

II. Responses to the Objections to the Claims

Claims 20, 21, and 24 are subject to formal objections. Claims 20 and 21 have been canceled and rewritten as new claims 102 and 103, which applicants respectfully submit address the objections to these claims. Claim 24 has been amended to correct the grammatical error that is the basis for the objection to this claim, which applicants respectfully submit addresses the objection to claim 24.

Accordingly, applicants respectfully submit that the objections to claims 20, 21, and 24 have been addressed, and respectfully request that they be withdrawn at this time.

III. Responses to the Obviousness-type Double Patenting Rejections

Claims 1, 5, 7, 10-17, 19-26, 28, 29, 31-35, 37-43, 45-58, 60-66, and 68-78 have been rejected under the judicially-created doctrine of obviousness-type double patenting on several bases. These rejections are summarized as follows:

- A. Claims 1, 5, 11, 15, 16, 17, 22, 28, 29, 31, and 32 have been rejected over claims 8 and 10 of U.S. Patent No. 6,117,681 (hereinafter "the '681 Patent");
- B. Claim 7 has been rejected over claim 8 of the '681 Patent in view of Mee & Brown (1990) 88 *Gene* 289-292 (hereinafter "Mee");
- C. Claims 10 and 12 have been rejected over claims 8 and 10 of the '681 Patent in view of Price *et al.* (1987) 84 *PNAS* 156-160 (hereinafter "Price");
- D. Claims 13 and 14 have been rejected over claim 8 of the '681 Patent in view of Miller *et al.* (1989) 7 *Biotechniques* 980-990 (hereinafter "Miller") and Panganiban & Temin (1984) 81 *PNAS* 7885-7889 (hereinafter "Panganiban");
- E. Claims 33-35, 38, 42, 43, 46-49, and 51-55 have been rejected over claims 8 and 10 of the '681 Patent in view of Mehigh *et al.* (1993) 71 *J Anim Sci* 687-693 (hereinafter "Mehigh");
- F. Claims 19, 20, 21, 23-25, 56, 57, 61, 65, 66, 68-72, and 74-78 over claims 8 and 10 of the '681 Patent in view of Couture *et al.* (1994) 5 *Human Gene Therapy* 667-677 (hereinafter "Couture");
- G. Claim 26 has been rejected over claims 8 and 10 of the '681 Patent in view of Longmore *et al.* (1993) 82 *Blood* 2386-2395 (hereinafter "Longmore") and Kay *et al.* (1993) 262 *Science* 117-119 (hereinafter "Kay");
- H. Claims 37 and 39 have been rejected over claims 8 and 10 of the '681 Patent in view of Mehigh and further in view of Price;
- I. Claims 40 and 41 have been rejected over claims 8 and 10 of the '681 Patent in view of Mehigh and further in view of Miller and Panganiban;

- J. Claim 45 has been rejected over claims 8 and 10 of the '681 Patent in view of Mehigh and further in view of Couture;
- K. Claim 50 has been rejected over claims 8 and 10 of the '681 Patent in view of Mehigh and further in view of Longmore and Kay;
- L. Claim 58 has been rejected over claims 8 and 10 of the '681 Patent in view of Couture and further in view of Mee;
- M. Claims 60 and 62 have been rejected over claims 8 and 10 of the '681 Patent in view of Couture and further in view of Price;
- N. Claims 63 and 64 have been rejected over claims 8 and 10 of the '681 Patent in view of Couture and further in view of Miller and Panganiban;
- O. Claim 73 has been rejected over claims 8 and 10 of the '681 Patent in view of Couture and further in view of Longmore and Kay;
- P. Claims 1, 5, 11, 17, 19-25, 28, 29, 31, 32, 56, 57, 61, 66, 68-72, and 74-77 have been rejected over claims 1-20 of U.S. Patent No. 7,022,319 (hereinafter "the '319 Patent") in view of Couture;
- Q. Claims 7, 16, 58, and 65 have been rejected over claims 1-20 of the '319 Patent in view of Couture and further in view of Mee;
- R. Claims 10, 12, 60, and 62 have been rejected over claims 1-20 of the '319 Patent in view of Couture and further in view of Price;
- S. Claims 13, 14, 63, and 64 have been rejected over claims 1-20 of the '319 Patent in view of Couture and further in view of Miller and Panganiban;
- T. Claims 33-35, 38, 43, 45-49, 51-55, and 78 have been rejected over claims 1-20 of the '319 Patent in view of Couture and further in view of Mehigh;
- U. Claims 7 and 39 have been rejected over claims 1-20 of the '319 Patent in view of Couture in view of Mehigh and further in view of Price;
- V. Claims 40 and 41 have been rejected over claims 1-20 of the '319 Patent in view of Couture in view of Mehigh and further in view of Miller and Panganiban;
- W. Claim 42 have been rejected over claims 1-20 of the '319 Patent in view of Couture in view of Mehigh and further in view of Mee;

- X. Claims 26 and 73 have been rejected over claims 1-20 of the '319 Patent in view of Couture and further in view of Longmore and Kay;
- Y. Claim 50: have been rejected over claims 1-20 of the '319 Patent in view of Couture in view of Mehigh and further in view of Longmore and Kay;
- Z. Claims 1, 5, 7, 11, 15, 19-26, 28, 29, 31-35, 38, 43, 45-58, 61, 66, and 68-78 have been rejected over claims 1, 3, 4, 8-10, and 13 of U.S. Patent No. 7,074,398 (hereinafter "the '398 Patent") in view of Couture;
- AA. Claims 10, 37, and 60 have been rejected over claims 1, 3, 4, 8-10, and 13 of the '398 Patent in view of Couture and further in view of Price;
- BB. Claims 10, 37, and 60 have been rejected over claims 1, 3, 4, 8-10, and 13 of the '398 Patent in view of Couture and further in view of Miller and Panganiban; and
- CC. Claims 10, 37, and 60 have been rejected over claims 1, 3, 4, 8-10, and 13 of the '398 Patent in view of Couture and further in view of Mee.

III.A. Response to the Rejections over the '681 and '319 Patents

Rejections A-O and P-Y listed above are based on the '681 Patent or on the '319 Patent. Applicants respectfully submit that these two patents are assigned to GSF-Forschungszentrum für Umwelt und Gesundheit GmbH (hereinafter "GSF"), which is also the assignee of the instant application.

Terminal disclaimers are submitted herewith with respect to the present U.S. patent application and U.S. Patent No. 6,117,681 and U.S. Patent No. 7,022,319. This is believed to obviate the obviousness-type double patenting rejections wherein these patents are cited.

In submitting these terminal disclaimers applicants do not acknowledge that the pending claims are obvious over the claims of the cited patents. Indeed, the Federal Circuit has noted: "[A Terminal Disclaimer] is not an admission of obviousness of the later filed claimed invention in light of the earlier filed disclosure for that is not the basis of the Disclaimer." Quad Environmental Technologies v. Union Sanitary District, 20 U.S.P.Q.2d 1392, 1394 (Fed. Cir. 1991).

The Federal Circuit further noted:

In legal principle, the filing of a Terminal Disclaimer simply serves the statutory function of removing the rejection of double patenting and raises neither presumption nor estoppel on the merits of the rejection. It is improper to convert this simple expedient "obviation" into an admission or acquiescence or estoppel on the merit.

Quad Environmental Technologies, 20 U.S.P.Q.2d at 1394-95.

Therefore, with the submission of the Terminal Disclaimers provided herewith, applicants are simply availing themselves of the statutory function of removing the double patenting rejection.

Accordingly, applicants respectfully submit that with the filing of the instant Terminal Disclaimers, claims 12-14, 16, 39-42, and 62-65 are believed to recite allowable subject matter, as all rejections of these claims have been addressed.

III.B. Response to the Rejection over the '398 Patent

Claims 1, 5, 7, 10, 11, 15, 19-26, 28, 29, 31-35, 37, 38, 43, 45-58, 60, 61, 66, and 68-78 have been rejected over claims 1, 3, 4, 8-10, and 13 of the '398 Patent" over Couture, in some instances in further view of Price, Miller and Panganiban, or Mee.

After careful consideration of the rejections and the Patent Office's bases therefor, applicants respectfully traverse the rejections and submit the following remarks.

Initially, the Patent Office appears to have applied a one-way obviousness analysis to the instant claims, which applicants respectfully submit is improper in the instant case. Particularly, M.P.E.P. § 804 sets forth the requirements for obviousness-type double patenting analysis when the cited patent results from a later filed application, and review of this section indicates that two-way obviousness analysis is warranted in analyzing the pending claims under the doctrine of obviousness-type double patenting.

To elaborate, M.P.E.P. § 804 states that "[a] rejection based on nonstatutory double patenting is based on a judicially created doctrine grounded in public policy so as to prevent the unjustified or improper timewise extension of the right to exclude granted by a patent" (citations omitted). Additionally, "[a] double patenting rejection of the obviousness-type... is 'analogous to [a failure to meet] the nonobviousness requirement of 35 U.S.C. 103' except that the patent principally underlying the double

patenting rejection is not considered prior art” (see M.P.E.P. § 804). Therefore, “the analysis employed in an obviousness-type double patenting rejection parallels the guidelines for analysis of a 35 U.S.C. 103 obviousness determination” (*Id.*).

Furthermore, applicants respectfully submit that M.P.E.P. § 804 states:

If the patent is the later filed application, the question of whether the timewise extension of the right to exclude granted by a patent is justified or unjustified must be addressed. A two-way test is to be applied only when the applicant could not have filed the claims in a single application and there is administrative delay. *In re Berg*, 46 USPQ2d 1226 (Fed. Cir. 1998).

Applicants respectfully submit that in the instant case, the cited patent (*i.e.*, the ‘398 Patent) issued from U.S. Patent Application Serial No. 09/058,546, filed April 10, 1998. The instant application was filed February 28, 1997. Thus, the cited ‘398 Patent issued from the later filed application.

Furthermore, the cited ‘398 Patent claims priority back to DK Patent Application 1157/95, filed October 15, 1995 through PCT/EP96/004447, filed October 11, 1996. The instant application claims priority back to DK Patent Application 1017/94, filed September 2, 1994 through PCT/EP95/003445, filed September 1, 1995. Thus, it is believed that the cited ‘398 Patent relates to subject matter that could not have been claimed in the instant application.

And finally, applicants respectfully submit that there was substantial administrative delay that occurred while the instant application was undergoing appeal. Particularly, applicants respectfully submit that a Notice of Appeal was filed in the instant application on April 26, 2005. The Appeal was decided on October 31, 2006. In the interim, the ‘398 Patent was allowed and issued. Given that the Patent Office was reversed with respect to all claims in the Decision by the Board of Patent Appeals and Interferences, it is believed that the instant application should have received a Notice of Allowance on October 26, 2004 rather than a Final Rejection. As such, it is further believed the later filed claims issued in the ‘398 Patent prior to the instant claims issuing as a patent as a result of administrative delay.

Summarily, applicants respectfully submit that all of the conditions for mandating two-way obviousness analysis are met in the instant application. The Patent Office has

not employed two-way analysis, and thus applicants respectfully submit that the instant obviousness-type double patenting rejections of claims 1, 5, 7, 10, 11, 15, 19-26, 28, 29, 31-35, 37, 38, 43, 45-58, 60, 61, 66, and 68-78 are based on an improper analysis, and thus are themselves improper and should be withdrawn.

Furthermore, applicants respectfully submit that if the proper two-way obviousness analysis had been performed, applicants respectfully submit that the analysis would have precluded the Patent Office from applying the instant rejections to the claims. While applicants do not acquiesce to the Patent Office's assertions with respect to the one-way analysis that has been performed, applicants respectfully submit that the second aspect of the proper two-way analysis, which relates to whether the claims of the '398 Patent are obvious over the instant application, has already been determined by the Patent Office during the prosecution of the application that issued as the '398 Patent.

To elaborate, applicants respectfully submit that during the prosecution of the application that issued as the '398 Patent (*i.e.*, U.S. Patent Application Serial No. 09/058,546), the Patent Office was aware of and considered the instant application, which is printed on the face of the '398 Patent. As a result, the Patent Office has already concluded that the claims of the '398 Patent are patentably distinct over the instant claims.

Therefore, applicants respectfully submit that the instant obviousness-type double patenting rejections of the instant claims are improper as having employed only a one-way obviousness analysis. Applicants further respectfully submit that when viewed in conjunction with the fact that the claims of the '398 Patent have already been examined in light of the instant application and found allowable, a proper two-way analysis of the instant claims would have precluded all of the remaining obviousness-type double patenting rejections.

Accordingly, applicants respectfully submit that the obviousness-type double patenting rejections of claims 1, 5, 7, 10, 11, 15, 19-26, 28, 29, 31-35, 37, 38, 43, 45-58, 60, 61, 66, and 68-78 over claims 1, 3, 4, 8-10, and 13 of the '398 Patent in view of Couture, in some instances in further view of Price, Miller and Panganiban, or Mee, are believed to be improper and should be withdrawn. Applicants further respectfully submit

that claims 1, 5, 7, 10, 11, 15, 19-26, 28, 29, 31-35, 37, 38, 43, 45-58, 60, 61, 66, and 68-78 are in condition for allowance, and respectfully solicit a Notice of Allowance to that effect.

IV. Discussion of the New Claims

New claims 102 and 103 have been added. These claims recite the elements originally recited in claims 20 and 21 (with updated claim dependency for claim 103). The cancelation of claims 20 and 21 and the replacement of the canceled claims with identical new claims 102 and 103 has been done to address a formal objection to claims 20 and 21 depending from claim 28. Thus, support for new claims 102 and 103 can be found in claims 20 and 21, and as such, no new matter has been added by the inclusion of new claims 102 and 103 in the instant application.

New claims 102 and 103 are believed to be distinguished over the cited references for the reasons set forth hereinabove with respect to the obviousness-type double patenting rejection over the '398 Patent in view of Couture (i.e., the combination of references over which claims 20 and 21 were rejected). Thus, applicants respectfully submit that claim 102 and 103 are believed to be in condition for allowance.

CONCLUSIONS

Applicants respectfully submit that claims 1, 5, 7, 10-17, 19, 22-26, 28, 29, 31-35, 37-43, 45-58, 60-66, 68-78, 102, and 103 are believed to be in condition for allowance, and a Notice of Allowance with respect to these claims is respectfully solicited.

If any small matter should remain outstanding after the Patent Examiner has had an opportunity to review the above Remarks, the Patent Examiner is respectfully requested to telephone the undersigned patent attorney in order to resolve these matters and avoid the issuance of another Official Action.

DEPOSIT ACCOUNT

The Commissioner is hereby authorized to charge any fees associated with the filing of this correspondence to Deposit Account No. 50-0426.

Respectfully submitted,

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